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EXAMINER

MACFARLANE, STACEY NEE

ART UNIT	PAPER NUMBER
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1649

NOTIFICATION DATE	DELIVERY MODE
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03/27/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/659,295	Applicant(s) SCHAEBITZ ET AL.	
	Examiner STACEY MACFARLANE	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,9,11-14,16-19 and 105-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-7, 9, 11-14, 16-19, 105-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/15/2009 has been entered.

Response to Amendment

2. Claims 1, 16 and 105-112 have been amended, claim 113 newly added, as requested in the amendment filed on 1/15/2009. Following the amendment, claims 1, 5-7, 9, 11-14, 16-19, 105-113 are pending in the instant application.

Claims 1, 5-7, 9, 11-14, 16-19, 105-113 are under examination in the instant office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on January 15, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1649

6. Newly added Claim 113 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the active method steps required in order for one of ordinary skill in the art to “identify a mammal suffering from traumatic brain injury” as claimed.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 5-7, 9, 11-14, 16-19, 105-113 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1, 105 and 113 recite methods encompassing administration of “a protein having at least 90% homology to SEQ ID NO:28 and G-CSF activity, mammalian G-CSF comprising one or more chemical substituents, human G-CSF comprising one or more chemical substituents, mammalian G-CSF fused to a second protein, human G- CSF fused to a second protein or combinations thereof”. Claims 5-7, 9, 11-14, 16-19, 106-112 are dependent claims and do not further limit the “protein having at least 90% homology to SEQ ID NO:28 and G-CSF activity, mammalian G-CSF comprising one or more chemical substituents, human G-CSF comprising one or

Art Unit: 1649

more chemical substituents, mammalian G-CSF fused to a second protein, human G-CSF fused to a second protein or combinations thereof", and are therefore included in the rejection. Additionally, Claim 11 recites the method further comprising administering "a hemodynamically active compound" and Claim 13 recites the method further comprising "an agent that facilitates passage ... over the blood brain barrier [(BBB)]". The claims do not require that the homologous proteins having G-CSF activity or that the chemical substituents, fusion proteins, hemodynamically active compound or agent that facilitates BBB transport possess any particular structure. Thus, the claims are drawn to genera of molecules defined merely by activity (e.g. "G-CSF activity", "hemodynamic" activity, or facilitating BBB transport) or by a structure that comprises, in part, mammalian or human G-CSF but for which there is no disclosed structure or structure-to-function description. Therefore, the claims encompass genera of molecules and the instant specification fails to describe the entire genera of molecules that are encompassed by these claims.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant is in possession of specific examples of GCSF: Some working examples utilize rat GCSF (Table 1), the disclosure also provides for specific formulations known in the art (paragraph [0057]) and various derivatives by manufacturers (e.g. Lenogastim from Roche, Granocyte from Chugai Pharma, Co. Ltd., Albugranin from Human Genome Sciences, or Neulasta from Roche/Amgen,

Art Unit: 1649

paragraph [0139]). The claims, however, encompass methods comprising administration of any protein having at least 90% homology to SEQ ID NO:28 and G-CSF activity, any mammalian G-CSF comprising one or more chemical substituents, any human G-CSF comprising one or more chemical substituents, any mammalian G-CSF fused to a second protein, any human G-CSF fused to a second protein, or any combination thereof. Thus, the claims are not limited to specific molecules with known structure. With respect to the “hemodynamically active compound” of Claim 11, there is no recitation within the disclosure of structure or distinguishing characteristics of the molecules encompassed by the genus. The specification also fails to provide adequate written description in the form of structure and/or structure-to-function characteristics that demonstrate possession of the encompassed genus of “agent(s) that facilitate passage” of any protein having at least 90% homology to SEQ ID NO:28 and G-CSF activity, any mammalian G-CSF comprising one or more chemical substituents, any human G-CSF comprising one or more chemical substituents, any mammalian G-CSF fused to a second protein, or any human G-CSF fused to a second protein across the BBB.

In order to provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of that genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claim is a

Art Unit: 1649

recitation of activity (e.g. "G-CSF activity") and or a disclosure that the molecule comprises, in part, any mammalian or human G-CSF. With regards to the recitation of a protein having at least 90% homology to SEQ ID NO: 28 and G-CSF activity, there is not even identification of any particular portion of the structure that must be conserved for said activity. As stated above, it is not even clear what molecules except those specifically recited in paragraphs [0057] and [0139] are encompassed by the claims. The specification fails to provide a representative number of species for the recited genera and, accordingly, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, the court clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed structure of, for example, the encompassed genera of proteins having at least 90% homology to SEQ ID NO: 28 and G-CSF activity, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of identifying activity. Adequate written description requires more than a mere recitation of activity and/or partial structure as part of the invention and a reference to a potential method of isolating or screening molecules that fulfill these requirements. The compound itself is

Art Unit: 1649

required with sufficient recitation of the physical and/or chemical properties or structure-to-function correlation that provides for the identification of the molecules within the encompassed genera. See *Fiers v Revel*, 25 USPQ2d 1601 at 1601 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification only provided for the bovine sequence. In the instant case, the claims encompass broad genera including proteins that are homologous to human G-CSF, chemically modified derivatives of human or mammalian G-CSF, or fusion proteins comprising in part human or mammalian G-CSF, hemodynamically active compounds, and agents that facilitate passage across the BBB, but the specification has not provided adequate written description for the molecules encompassed by the claims. Therefore, the claims are rejected.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. As currently amended, Claims 1, 9, 17, 18 and 113 are rejected under 35

U.S.C. 102(b) as being anticipated by Heard *et al.* (2004) as evidenced by NCBI protein

Art Unit: 1649

accession number P09919 (1989), and Whalen *et al.*, Critical Care Medicine, 27(5):

1014-1018, May 1999, for reasons of record in the Office action mailed May 22, 2008.

On pages 6-8 of Remarks filed January 15, 2009, Applicant traverses the rejection on the following grounds: 1) Heard *et al.* does not teach "treating traumatic brain injury (TBI)" but rather teaches the prophylactic treatment of "nosocomial infections in intubated patients with acute TBI or intracerebral hemorrhage" (page 6 Remarks) which is, "at best, a side effect of the intubation which is sometimes performed during TBI or cerebral hemorrhage" (page 7); and 2) Heard teaches a "randomized, placebo-controlled, double-blind multicenter study" in which patients with TBI or intracerebral hemorrhage are treated with G-CSF. Applicant states,

"While it is possible that one intubated patient may have been one with acute TBI and that one patient may have received the drug in question, the mere possibility that something may have happened to a patient is not a sufficient basis to reject a claim based on inherent anticipation. The law requires that 'Inherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *Continental Can Co. v. Monsanto Co.* quoting from *In re Oelrich* (Remarks, page 7).

Lastly, Applicant traverses on the grounds that claim 1 has been amended to define that the mammals being treated are those "suffering from TBI" and that Heard does not present a beneficial effect on the symptoms of TBI nor even discuss such an effect, nor does Heard describe or even suggest that a patient suffering from TBI be targeted as in the claimed method. While these arguments have been carefully considered they are not found persuasive to overcome the rejection for the following reasons.

Claims are drawn to a method of treating traumatic brain injury (TBI) in a mammal comprising administering mammalian and/or human G-CSF. The Heard *et al.*

Art Unit: 1649

prior art fully describes methods comprising administering human G-CSF to patients with acute traumatic brain injury or cerebral hemorrhage. Specifically, the Heard prior art teaches administration of recombinant human G-CSF (brand name Filgrastim, which the NCBI reference teaches as 100% identical to that of SEQ ID NO: 28 of the instant specification) and demonstrate that filgrastim has the effect of alleviating bacteremia.

The Whalen et al. prior art is relied upon as evidence that the methods as disclosed within the Heard reference are recognized by one of ordinary skill in the art as targeting TBI patients and treating symptoms of TBI comprising administration of G-CSF. The Whalen et al. reference is a Commentary upon the Heard findings. In general, the reference is critical of Heard et al. stating that while "G-CSF may be a useful agent to prevent infection in head-injured patients" the "systemic administration of G-CSF to patients with TBI risks increasing acute inflammation in injured brain". Therefore, the Whalen reference demonstrates that the Heard findings teach a beneficial effect of treatment for TBI patients, and that systemic administration would inherently affect the injured brain.

The method of the instant claims does not distinguish in any way over the method of the Heard prior art. As currently amended the claims do not require any specific step or other distinguishing criteria necessary for identifying TBI patients. Nor do the claims stipulate specific criteria by which "treatment" of TBI is assessed. Furthermore, the quotation in Remarks from *In re Oelrich* is taken out of context, in that the remainder of the text states, "If, however, the disclosure is sufficient to show that the

Art Unit: 1649

natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient". *In re Oelrich and Divigard*, 212 USPQ 323, CCPA 1981). Since the claims for the treatment of TBI comprise the sole active step of administering mammalian/human G-CSF to a mammal/human patient suffering from traumatic brain injury and do not require any specific result, then and the limitations of this method are fully described within the Heard prior art and the natural result flowing from the operation of the method as taught would be the effect of treatment. Thus, instant claims fail to distinguish over the method of the prior art and the claims are rejected.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 5-7 stand as rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. as applied to claims 1, 9, 17, 18 and 113 above, and further in view of Brines et al. (2000) for reasons of record in the previous Office action mailed May 22, 2008.

On page 8 of Remarks filed January 15, 2009, Applicant traverses the rejection on the grounds that because the primary reference, Heard, is silent about treating the underlying condition of TBI, then each of the combinations subsequently fail.

In above sections of the instant office action Examiner provides reasoning for Claims 1, 9, 17, 18 and 113 standing as rejected under 35 U.S.C. 102(b) as being anticipated by Heard *et al.* (2004). Briefly, the Heard *et al.* prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients with traumatic brain injury. The Heard reference does not teach the method further comprising administering one or more additional hematopoietic factors, nor specifically erythropoietin as required by instant claims 5, 6, and 7, however, the Brine *et al.* reference, however, teaches that methods for the treatment of traumatic brain injury comprising administering erythropoietin were well-known in the art prior to filing. Thus, the invention is *prima facie* obvious for reasons of record in the Paper mailed May 22, 2008 and the rejection is maintained.

13. Claims 12 and 16 stand as rejected under 35 U.S.C. 103(a) as being unpatentable over Heard *et al.*, and further in view of Deleuze (2000) for reasons of record in the Paper mailed May 22, 2008.

On page 8 of Remarks filed January 15, 2009, Applicant traverses the rejection on the grounds that because the primary reference, Heard, is silent about treating the underlying condition of TBI, then each of the combinations subsequently fail.

In above sections of the instant office action Examiner provides reasoning for Claims 1, 9, 17, 18 and 113 standing as rejected under 35 U.S.C. 102(b) as being anticipated by Heard *et al.* (2004). Briefly, the Heard *et al.* prior art teaches a method

Art Unit: 1649

for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients with traumatic brain injury. The Heard reference does not teach the method further comprising administering tissue plasminogen activator as required by instant claim 12. The Deleuze reference, however, teaches treatments of traumatic brain injury comprising administration of tissue plasminogen activator were known in the art. Therefore, the invention as a whole is *prima facie obvious*, if not actually anticipated by the reference and the rejection is maintained.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heard, and further in view of Morita-Fujimura (1999) for reasons of record in the Paper mailed May 22, 2008.

On page 8 or Remarks filed January 15, 2009, Applicant traverses the rejection on the grounds that because the primary reference, Heard, is silent about treating the underlying condition of TBI, then each of the combinations subsequently fail.

Above, Examiner provides reasoning for Claims 1, 9, 17, 18 and 113 standing as rejected under 35 U.S.C. 102(b) as being anticipated by Heard *et al.* (2004). Briefly, the Heard *et al.* prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients with traumatic brain injury. The Heard reference does not teach the method further comprising an anti-apoptotic agent defined within the specification as "e.g. inhibitors of caspases".

Art Unit: 1649

However, Morita-Fujimura et al. teach the administration of inhibitors of caspases for the treatment of traumatic brain injury in mammals was known in the art prior to filing.

Therefore, the invention as a whole is *prima facie obvious*, if not actually anticipated by the reference for reasons of record and the rejection is maintained.

15. Claims 105-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. as applied to claims 1, 9, 18 and 113 above, and further in view of Neupogen® (Filgrastim) Amgen product information, published April 2, 1998 for reasons of record in the Office Action mailed November 10, 2008.

On page 8 of Remarks filed January 15, 2009, Applicant traverses the rejection on the grounds that because the primary reference, Heard, is silent about treating the underlying condition of TBI, then each of the combinations subsequently fail.

The Heard et al. prior art teaches a method comprising administering recombinant human G-CSF that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients with traumatic brain injury. The Heard reference, however, administers GCSF subcutaneously and does not teach the method comprising intravenous administration. The product information published by the maker of commercially available human GCSF, Amgen, prior to filing indicate that Filgrastim could be interchangeably administered by oral, intravenous, subcutaneous, or intraperitoneal routes with no significant difference in effect. In the instant case, the problem to be solved is the route of administration and the art demonstrates that there are a finite number of ways to administer and does not indicate any differing effects by

Art Unit: 1649

either route. Therefore, it would have been obvious to one of ordinary skill in the art to combine the method as taught by Heard et al., with the routes of administration as taught by the product manufacturer and the invention as a whole is *prima facie* obvious if not anticipated by the prior art.

16. Claims 109 and 110 stand as rejected under 35 U.S.C. 103(a) as being unpatentable over Heard, and further in view of Curran and Goa (2002) for reasons of record in the Paper mailed May 22, 2008.

On page 8 of Remarks filed January 15, 2009, Applicant traverses the rejection on the grounds that because the primary reference, Heard, is silent about treating the underlying condition of TBI, then each of the combinations subsequently fail.

The instant office action sets forth Examiner's reasoning for Claims 1, 9, 17, 18 and 113 standing as rejected under 35 U.S.C. 102(b) as being anticipated by Heard *et al.* (2004). Briefly, the Heard et al. prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients with traumatic brain injury. The Heard reference does not teach the method further comprising administering a mammalian (human) G-CSF comprising one or more chemical substituents as required by instant claims 109 and 110. The Curran and Goa reference, however, teach that, prior to filing, pegylated filgrastim was known in the art as a substitute for the filgrastim used in the Heard reference and that this chemically substituted version of filgrastim confers specific advantages for administration to

Art Unit: 1649

patients. A skilled artisan would have deemed it obvious to combine the teachings of the reference, and the rejection is maintained.

17. Claims 111 and 112 stand as rejected under 35 U.S.C. 103(a) as being unpatentable over Heard, and further in view of MacVittie et al. (2000) for reasons of record in the Paper mailed May 22, 2008.

On page 8 of Remarks filed January 15, 2009, Applicant traverses the rejection on the grounds that because the primary reference, Heard, is silent about treating the underlying condition of TBI, then each of the combinations subsequently fail.

Above, Examiner provides reasoning for Claims 1, 9, 18 and 113 standing as rejected under 35 U.S.C. 102(b) as being anticipated by Heard *et al.* (2004). Briefly, the Heard et al. prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients with traumatic brain injury. The Heard reference does not teach the method further comprising administering a mammalian (human) G-CSF fused to a second protein as required by instant claims 111 and 112. The MacVittie et al., reference, however, teaches that chimeric IL-3/G-CSF fusion proteins, termed Myelopoiетins in the art, were known as substitutes for G-CSF prior to filing, and that these Myelopoiетins display a more favorable pharmacodynamic profile than G-CSF alone. Therefore, a skilled artisan would have been motivated to combine the teachings and the rejection is maintained because the invention as a whole is *prima facie* obvious.

Double Patenting

18. Applicant is advised that should claim 12 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

19. No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-W and ALT F 5:30 to 3:30, TELEWORK-Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1649

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649